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Docket No.: BSX 302 US1-REI/10408803

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Jeffrey M. LEIDEN *et al.*

Art Unit: 1632

Application No.: 10/726,258

Filed: December 1, 2003

Examiner: Ann Marie Baker

For: LONG-TERM EXPRESSION OF
ERYTHROPOIETIN AND GROWTH
HORMONE BY TRANSFORMING MUSCLE
CELLS

RESPONSE TO DECISION ON PETITION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is in response to the Examiner's comments in a Decision on Petition mailed June 29, 2004 regarding the patent term in this re-examination application.

While a Petition Under 37 C.F.R. 1.55 and 1.78 for an Unintentionally Delayed Claim to Priority may be an inappropriate means to amend the specification to indicate that it is a national stage entry of a PCT application, Applicants wish to make clear that they disagree with the Examiner's comments that the patent term of this reissue application if granted, or the patent term of the parent Patent No. 6,613,319, will be calculated from the filing date of the provisional application 60/024,511 23 filed 23 August 1996. The patent term of the parent patent and the reissue patent should be calculated from the international filing date, i.e., 22 August 1997, and not the filing date of the provisional application, i.e., 23 August 1996.

U.S. patent application no. 09/091,134 gave rise to U.S. Patent 6,613,319, which is the subject of this reissue application. This reissue application was filed to amend the specification such that it identified the application as a national stage entry under 371 of PCT/US97/14764. The PCT information, although acknowledged by the USPTO during prosecution, was not

recited on the cover page of the patent and applicants did not amend application no. 09/091,134 to refer to the PCT application.

Applicants' amendment to the specification of this reissue application recites:

"This application is a [continuation in part] national stage application of International application No. PCT/US97/14764, filed August 22, 1997, which claims the benefit of provisional U.S. Ser. No. 60/024,511, filed [Aug.] August 23, 1996, the disclosure of which [is] are incorporated herein by reference.

The USPTO in its Decision on Petition mailed December 16, 1998 acknowledged that application no. 09/091,134, met the requirements for entry into the national stage in the U.S. as set forth in 35 U.S.C. 371 and has an international filing date of 22 August 1997 under 35 U.S.C. 363, and a 35 U.S.C. 102(e) and 371(c) date of 23 June 1998. Yet the cover page of the issued patent does not recite the PCT information. The first line of the 09/091,134 application also fails to recite this information. Thus one reading U.S. Patent No. 6,613,319 would perceive an apparent gap in the chain of priority back to the provisional application and it would appear that the U.S. 09/091,134 application was not filed within one year of the filing date of the provisional application. Thus the amendment to the specification clarifies the priority claim and clearly establishes the chain of priority.

Regarding applicants' priority claim to the provisional application 60/024,511 under 35 U.S.C. 119(e): Section 4503 of the American Inventors Protection Act of 1999 amended 35 U.S.C. 119(e) to state that:

No application shall be entitled to the benefit of an earlier filed provisional application under this subsection unless an amendment containing the specific reference to the earlier filed provisional application is submitted at such time during the pendency of the application as required by the Director. The Director may consider the failure to submit such an amendment within that time period as a waiver of any benefit under this subsection. The Director may establish procedures including the payment of a surcharge to accept an unintentionally delayed submission of an amendment under this section during the pendency of the application.

Applicants amended the 09/091,134 application to contain a "specific reference to the earlier filed provisional application." The application was also amended to recite the priority

claim to the provisional application upon entering national stage and thus the amendment was “submitted at such time during the pendency of the application as required by the Director.” In the Decision on the Petition, the Examiner acknowledges the priority claim was made: However, the Examiner contends that the priority claim was made under 35 U.S.C. 120 not 119(e) because Applicants identified the 09/091,134 application as a “continuation in part” of the provisional application. As such, it is the Examiner’s position that the term of the patent is calculated from the date of the provisional application and not the date of the international application. Applicants respectfully disagree.

Applicants’ priority claim to the U.S. Provisional application is and was always intended to be a claim for priority under 35 U.S.C. 119(e). Therefore applicants are not “correcting” the priority claim to the provisional application by the amending the specification to eliminate the confusing language that identifies the non-provisional application as a continuation-in-part of the provisional application. Rather applicants are clarifying the language of the priority claim to make clear the priority claim is under 119(e).

MPEP 201.11, subsection B, states:

“The relationship (i.e., continuation, divisional, or continuation-in-part) is not required and should not be specified when a prior provisional application is being claimed under 35 U.S.C. 119(e). No relationship should be specified because whenever a priority claim to a provisional application under 35 U.S.C. 119(e) is made, it is implicit that the relationship is “nonprovisional application of a provisional application.” If a relationship between a prior provisional application and the non-provisional application is submitted, it may be unclear whether the applicant wishes to claim the benefit of the filing date of the provisional application under 35 U.S.C. 119(e) or 120. Thus applications seeking to claim the priority to a provisional application under 35 U.S.C. 119(e) should not state that the application is a continuation of a provisional application or that the application claims 35 U.S.C. 120 benefit to a provisional application.

The Examiner contends:

Of particular relevance to the instant situation is MPEP 201.11, subsection B entitled “Reference to Prior Provisional Application” which indicates that where, as here, a relationship was stated between the prior provisional and subsequent non-provisional application when the priority claim was made, such is construed as a claim for benefit under section 120 of the

prior provisional and not a section 119(e) claim for benefit. The distinction is that when a claim for benefit of a prior provisional – or non-provisional – application is made under 120, the 20 year term for the referencing patent is measured from the filing date of the prior provisional or prior nonprovisional, see 35 U.S.C. 154(a)(2) whereas when the claim for benefit of the same provisional application is made under section 119(e), the term of the referencing patent is not measured from the filing date of the provisional application, see 35 U.S.C. 154(a)(3).

(June 29, 2004 Decision page 3, emphasis added)

Applicants have quoted MPEP 201.11 *supra* and it is noted that this passage indicates that the relationship (i.e., continuation, divisional, or continuation-in-part) SHOULD NOT be specified when a prior provisional application is being claimed under 35 U.S.C. 119(e) because it may be unclear whether the applicant wishes to claim the benefit of the filing date of the provisional application under 35 U.S.C. 119(e) or 120. The passage does not preclude the recitation of a relationship (i.e., continuation, divisional, or continuation-in-part) when a prior provisional application is being claimed under 35 U.S.C. 119(e).

As MPEP 201.11 predicted, the Examiner in the June 29, 2004 Decision misunderstood applicants' intent to claim priority to the provisional application under 119(e) and concludes that the relationship specified in the first line of the application must be construed as a priority claim under 120 rather than under 35 U.S.C. 119(e).

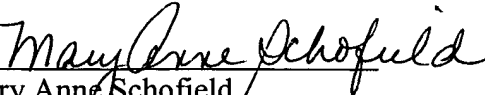
It is and always has been applicants' intent to claim the priority of the provisional application under 35 U.S.C. 119(e). Applicants identified the provisional application by its serial no. and filing date and identified it as a provisional application during the pendency of the 09/091,134 application. Applicants did not identify the priority claim as one under 35 U.S.C. 120. Nor did the USPTO recognize the priority as a claim under 120 during prosecution. None of the Office Actions in 09/091,134 indicate that the prosecuting Examiner ever considered the claim for priority to the provisional application to be a priority claim under 35 U.S.C. 120.

The cover page of the issued patent under "Related U.S. Applications Data" recites "[60] Provisional application no. 60/024,511, filed on Aug. 23, 1996". The cover page omits the "continuation in part" language, as does applicants amendment, which eliminates the source of confusion.

Applicants believe no fee or request for extension of time are due with this filing. However, if such a fee is due or a request for an extension of time is required applicants authorize the Commissioner to deduct any missing or insufficient fee from Deposit Account No. 06-2375, under Order No. BSX 302-US1-REI/10408803 and applicants request that any necessary extensions of time be granted.

Dated: October 28, 2004

Respectfully submitted,

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